RISK EVALUATION PROGRAM OVERVIEW, SCHEDULE, AND FIRST 10 CHEMICALS

ISSUE SUMMARY:

The Risk Evaluation process is the second step, following Prioritization and before Risk Management, in EPA's existing chemical process under TSCA. The purpose of risk evaluation is to determine whether a chemical substance presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. When conducting risk evaluations, EPA must evaluate hazard and exposure, exclude consideration of costs or other nonrisk factors, and make decisions based on the best available science and weight-of-scientific-evidence, among other requirements.

TSCA required that EPA have 20 high-priority substances undergoing risk evaluation by December 22, 2019. EPA announced the final priority designation of these 20 chemicals in December 2019 and finalized the scopes in September 2020. EPA has 3-3.5 years (from initiation in December 2019), to complete the risk evaluations.

The finalization of the "framework" rule for TSCA risk evaluations as well as the risk evaluations for the first 10 chemicals to undergo risk evaluation have necessitated major policy and science policy decisions. This included the exclusion of "legacy uses," or those uses for which the chemical is no longer being manufactured, processed or distributed for that use, and "associated disposal," from evaluation. As a result of the December 2019 9th Circuit Court of Appeals decision (*Safer Chemicals Healthy Families et al. v. EPA*, 943 F.3d 397), EPA cannot categorically exclude these activities from the risk evaluations. It is likely additional policy decisions will be litigated.

Another major policy decision is how the Agency has chosen to address the relationship between TSCA risk evaluations and other EPA administered statutes (e.g., Clean Water Act, Safe Drinking Water Act, Clean Air Act, and Resource Conservation and Recovery Act). EPA is exercising its TSCA authorities to tailor the scope of its risk evaluations, rather than focusing on environmental exposure pathways addressed under other EPA-administered statutes or regulatory programs or risks that could be eliminated or reduced to a sufficient extent by actions taken under other EPA-administered laws. More specifically, TSCA section 9(b)(1) requires the agency to coordinate actions under TSCA with actions under other EPA-administered federal laws, and this coordination can be crucial in helping enable the EPA to carry out its considerable new workload within limited timeframes. To facilitate this conversation across the Agency's various media divisions, the Administrator has requested the formation of the TSCA Coordinating Committee.

UPCOMING MILESTONES:

EPA issued final risk evaluations for three of the first 10 chemicals evaluated– methylene chloride, 1-bromopropane, and cyclic aliphatic bromide cluster (HBCD). The Agency is scheduled to finalize risk evaluations for most of the remaining seven – Pigment Violet-29, 1,4-dioxane, carbon tetrachloride, trichloroethylene, perchloroethylene, asbestos, and N-methylpyrrolidone – prior to the end of 2020.

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BACKGROUND:

TSCA requires EPA to evaluate the safety of existing chemicals (i.e., those already in the marketplace) through a three-staged process of prioritization, risk evaluation, and, where warranted, risk management. The purpose of risk evaluation is to determine if a chemical substance, under the conditions of use, present unreasonable risk to the environment or health.

Prioritization, as described in the Prioritization Rule, is a process to screen chemicals and culminates with the designation of a chemical as either high-priority for risk evaluation or low-priority. High-priority substances move to the risk evaluation process in accordance with the statute and the risk evaluation rule. EPA must publish a draft scope for public comment, and the final scope within 6-months of initiating the risk evaluation. EPA has three years, with a possible 6-month extension, to complete the risk evaluation. During this time EPA must publish a draft risk evaluation, allow for public comment, and conduct an independent peer review. The final risk evaluation makes an unreasonable risk determination for each condition of use included in the scope. For those uses for which unreasonable risk is determined, the Agency must begin risk management. For those uses that present no unreasonable risk, the determination is issued by order and is a final Agency action that may be subject to litigation.

KEY EXTERNAL STAKEHOLDERS:

☒ Congress ☒ Industry ☒States ☒ Tribes ☐ Media ☒ Other Federal Agency
☒ NGO ☒ Local Government ☐ Other: _____

A range of stakeholders, including industry, NGOs, and state and local governments have provided comments on the first 10 risk evaluations. Other federal agencies have equities in many of the chemicals and are invited to review all draft and final documents associated with the risk evaluations.

MOVING FORWARD:

Environmental NGOs and a labor union sued EPA in response to the final methylene chloride risk evaluation published in June 2020. Additional legal challenges are expected for several of the remaining first 10 risk evaluations. These suits are expected to focus primarily on policy decisions associated with the included/excluded conditions of use, the treatment of exposure pathways covered under other EPA administered statutes, and the assumptions regarding use of personal protective equipment in occupational settings. The outcome of these legal challenges will greatly impact all other subsequent risk evaluations.

LEAD OFFICE/REGION: OCSPP	OTHER KEY OFFICES/REGIONS: ORD, OGC, OCHP, OP, OECA, OLEM, OAR, Regions